

REMARKS

Claims 1-31 are pending in the application.

Claims 3-5, 14-16 and 31 are objected to but would be allowed if rewritten in independent form. Claims 3-5 have been rewritten as new claims 32-34, claims 14-16 have been rewritten as new claims 35-37, and claim 30 has been amended to include the subject matter of claim 31. Therefore, such claims are now clearly in condition for allowance. Claim 31 has been canceled without prejudiced.

Claims 1-2 and 6 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,139,555 to Hart. The applicant respectfully traverses the Examiner's rejection for the following reasons.

First, Hart fails to teach "inserting a flexible instrument into a human body." Hart states that "[i]n a preferred embodiment, the outer body 12 is rigid, however it may also be made from a semi-compliant or flexible material to allow *some* flexibility along the axis 22." This statement does not imply an entirely flexible instrument, only that there is some 'give' along the axis of the outer body. In fact, the Hart device requires a relatively large diameter, presumably rigid, push rod 58 (Fig. 1) extending through the outer body 12 which is operated for the advancement of clips. The push rod prevents the instrument from being truly flexible.

Second, Hart fails to teach deforming the first and second clips so that portions thereof *pierce* tissue. The clips in Hart are blunt-tipped and are only shown placed on tissue so as to surround or ligate tissue. Given that the Hart clips are not designed for piercing, Hart fails to provide any teaching or suggestion for using the device in accord with the claimed method.

For the foregoing reasons, Hart fails to anticipate or suggest the claimed method of the invention.

Claims 1-2, 11-13 and 17 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,395,030 to Kuramoto et al. The applicant respectfully traverses the Examiner's rejection for the following reasons.

Regarding claims 1 and 2, Kuramoto fails to teach a flexible instrument. Kuramoto teaches an instrument with a shaft defined by a rigid insertion section 283 joined to a rigid distal end portion 287 by a bending portion 286 which, as shown in Fig. 58A, is simply a mechanical hinge. None of the portions, including the bending portion, is *flexible*; i.e., pliant. While all flexible things are bendable, not all bendable things are necessarily flexible, as shown by the example of Kuramoto.

Also, regarding claims 1 and 2, Kuramoto fails to teach deforming the first and second clips so that portions thereof *pierce* tissue. Kuramoto is silent on this matter and

does not provide a teaching regarding first advancing a clip over tissue and then deforming a clip to pierce the tissue.

Regarding claim 11, Kuramoto fails to provide any teaching with respect to whether either of the jaws is rotatable relative to the other, or whether one of the jaws has a clip guide. Further, Kuramoto also fails to teach whether the flexible clip-advancing element is flexible, as it may also be hinged.

Regarding claims 12 and 13, Kuramoto provides no teaching or suggestion whether “one of said jaws includes an anvil, and said operating said handle to advance said clip causes a portion of said clip to deform against said anvil” or the type of deformation claimed in claim 13. In fact, the clip applier in Figs. 58A-C appears to be of the type where the clips are not deformed during or post-application.

Regarding claim 17, which requires inserting the instrument through an endoscope, Kuramoto fails to provide any teaching or suggestion therefor. In fact, the Kuramoto device includes its own optical viewing system (290, 291 used in conjunction with 296, 269) teaching away from its use with an endoscope.

For the foregoing reasons, Kuramoto fails to anticipate or suggest the claimed invention.

While the claims are not anticipated for the reasons advanced above, in order to expedite allowance claim 1 has been amended to state that the device is sufficiently flexible to be bent through 180°. This is not suggested by Hart (only “some flexibility along the axis”) or Kuramoto (a hinge without such degree of freedom). Also, new claim 38 more narrowly claims the method with a device sufficiently flexible to be bent through 360°. Claim 1 has also been amended to state that the clip is advanced parallel to the tissue layers, which is discussed further below with respect to claims 7-10.

Claims 7-10 and 18-29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Kuramoto in view of U.S. Pat. No. 5,271,543 to Grant et al. The applicant respectfully traverses the rejection for the following reasons.

The Examiner states that Kuramoto suggests applying a force with hydraulic pressure along an inner tube with sufficient force to push staples or fasteners or clips to secure tissue, and that Grant suggest forming the outer tubular member from a flexible coil and providing an inner flexible member to maintain a stiff shaft when in a curved configuration. The applicant traverses the rejection for the several reasons.

First, claims 7-10 depend from claim 1 which as amended requires advancing the clips parallel to the tissue layers. Pusher wire 71 (referenced by the examiner) is only used in a stapler embodiment (Fig. 10) of Kuramoto where the staples are pierced through the tissue perpendicular to the tissue layers. Grant is a similar type device.

There is certainly no suggestion for the limitation of claims 7-10 where the clip is advanced parallel to the tissue layers.

Second, in the embodiment of Kuramoto with the pusher wire 71 (Fig. 10), the stapler does not include *jaws*, one of which is *rotatable* relative to the other. Thus, there are no jaws which clamp tissue prior to advancing a clip over clamped target tissue, as required by claims 18-21. Further, claims 7-10 and 18-21 require specific forces to *advance a clip*. It is not clear why the inner cable and outer coil of Grant would be incorporated into the device of Kuramoto to effect such pushing force. In Grant, such elements are useful to pull the anvil relative to the stapler head and to fire and bend the arm of staples. However, in Kuramoto, a short, stiff but hinged, clip applier is provided. The clips need only be pushed into the arms. There is no need for the assembly in Grant to be incorporated in Kuramoto, as it fails to address any need in the Kuramoto device. (In the long flexible endoscopic instrument of the invention, consideration must be given to issues which are not a concern to Kuramoto.)

Third, claim 22 has been amended for clarity to indicate that by “endoscopic instrument” what is meant is an instrument that can be inserted into a lumen of an endoscope. The Kuramoto device of Fig. 10 includes a stapling head with staple applier 5 and anvil 6 which are far too large for placement through an endoscopic lumen.

Fourth, claim 26 requires “providing a compressive force to said tubular member when moving said inner member *distally* relative to said outer tubular member.” In

Grant, if any compressive force is applied to the outer tubular member, apparently it would only occur when the inner member is moved *proximally* relative to the outer tubular member, not during relative distal movement.

Fifth, claim 27 requires “providing a compressive force to the outer tubular member to increase a tensile limitation of the outer tubular member.” The examiner states that when the coils of Grant are tensioned they provide a compressive force to the outer tubular member. It is believed that this is not accurate. Rather, the firing cable 82 (outer member) is placed in compression and the tension-torsion cable 84 (inner member) is placed in tension in a manner which *does not increase the tensile limitation of the outer tubular member*. The outer tubular member remains in compression without being subject to tensile forces.

Sixth, claim 28 requires “operating said handle to create a tensile force of at least 500 grams at said distal end of said outer tubular member.” Again, in Grant, apparently the tensile load will be created at the distal end of the inner member. The outer tubular member 82 is for applying compressive forces.

Seventh, claim 29 has been amended for clarity to require that the instrument include a distal end sized to be inserted through a lumen of an endoscope and specifically requires inserting the instrument through a lumen of an endoscope and into the human body. This is not shown or suggested by the cited art. In addition, neither of the references teaches rotatable jaws or a clip guide on a jaw.

For the foregoing reasons, claim 7-10 and 18-29 are allowable over the art of record.

In light of all of the above, it is submitted that all claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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